REMARKS

The Applicants request reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Amendments to the Claims

This amendment adds, changes and/or deletes claims in this application. A detailed listing is presented, with an appropriate defined status identifier, of all claims that are or were in the application, irrespective of whether the claim(s) remain under examination.

In order to advance prosecution, the Applicants have requested the cancellation of claims 1-4, 7, 9, 10, 12, 13, 16, 17, 20, 21, 23, 25, 28, 29, and 33-35, without disclaimer or prejudice to further prosecution.

In order to advance prosecution, claims 5, 11, 15, 19, 22, and 24 are currently amended.

In particular, claim 5 is amended to recite "the macromonomer contains at least one pendant Z"; "n is from 50 up to but not including 100%"; and "the macromonomer is curable in vivo and when polymerized to form a cured polymer, the polymer has an elasticity (E) modulus between 0.1 and 5 kPa." Support for the phrase "the macromonomer contains at least one pendant Z" is provided, for example, in original claim 5 and in the specification at page 4, lines 11-13. Support for the phrase "n is from 50 up to but not including 100%" is provided, for example, in original claim 17 and in the specification at page 5, line 9. Support for the phrase "the macromonomer is curable in vivo and when polymerized to form a cured polymer, the polymer has an elasticity (E) modulus between 0.1 and 5 kPa" is provided, for

example, in original claims 24 and 28 and in the specification at page 9, lines 10-13 and 25-27.

Claim 11 is amended to depend from claim 5 in view of the fact that claim 9 has been cancelled.

Claim 15 is amended to omit recitation of the phrase "and other substituted atoms."

Claim 19 is amended to recite that "the total molar percentage of m + p + q + s is less than 1%." Support for this amendment is provided, for example, in the specification at page 15, lines 13-15.

Claims 22 and 24 are amended to depend from claim 5 in view of the fact that claim 1 has been cancelled.

Claim 24 is amended to omit recitation of the phrase "and an elasticity (E) modulus between 0.1 and 5 kPa" in view of the fact that claim 5 has been amended to incorporate this phrase.

After the claims are amended as set forth above, claims 5, 8, 11, 14, 15, 18, 19, 22, 24, 27, and 32 are pending in the application.

II. Claim Objections

Claims 5, 21, and 34 are under objection.

Claim 5 is objected to for reciting a variable "defined as having an upper limit of 100%" where "the polymer would have no pendant crosslinkable groups as claim 1 already requires." Claim 5 has been amended to recite the phrase "n is from 50 up to but not including 100%."

Claims 21 and 34 have been cancelled obviating the objection.

For these reasons, reconsideration and withdrawal of the claim objections are requested.

III. Claim Rejections – 35 U.S.C. § 112, second paragraph

Claim 25 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being "incomplete for omitting essential steps, such omission amounting to a gap between the steps."

Claim 25 has been cancelled obviating the rejection.

IV. Claim Rejections – 35 U.S.C. § 102(e) over Qureshi *et al.*

Claims 1, 20, 22, 27-29, 33, and 35 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Qureshi *et al.*, (U.S. published application no. 2003/0092866) (hereinafter "Qureshi"). The Applicants respectfully traverse the rejection in view of the foregoing amendments and for the following reasons.

Claim 1 has been cancelled and the pending claims depend either directly or indirectly from claim 5 which does not stand rejected under Qureshi. The Office Action has acknowledged that Qureshi "may perhaps not disclose all of these requirements [of claim 5] simultaneously." (*See* Office Action dated July 5, 2007, page 4) (hereinafter "Office Action").

For these reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e) over Qureshi are requested.

V. Claim Rejections – 35 U.S.C. §103(a) over Qureshi *et al.*

Claims 5, 7-9, 14-20, 22, 27-29, 33, and 35 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Qureshi. The Applicants respectfully traverse the rejection in view of the foregoing amendments and for the following reasons.

Qureshi does not teach or suggest the subject matter of the claims as amended. In particular, claim 5 has been amended to recite "the macromonomer is curable in vivo and when polymerized to form a cured polymer, the polymer has an elasticity (E) modulus between 0.1 and 5 kPa." Qureshi does not teach or suggest a macromonomer having the recited properties.

First, Qureshi is directed to a different problem. The presently claimed subject matter relates to macromonomers that are curable in vivo and form a polymer having desirable elasticity for use as an intraocular lens (*e.g.*, "an elasticity (E) modulus between 0.1 and 5 kPa" as recited in the claims).

In contrast, Qureshi relates to "pultrusion" which means "a method of drawing a plurality of fibrous reinforcement[s] coated with a binder solution through a heated die in order to shape the fibrous reinforcement[s] and binder into a unitary article of desired shape." (*See* Qureshi, paragraph [0002]). In particular, Qureshi states that "[t]he invention is directed to a ***high strength*** pultrusion resin composition comprising a phenolic resin and an elastomeric component." (*See* Qureshi, paragraph [0007] (emphasis added)). Qureshi further states that "[t]he elastomeric component is formed from the reaction product of a polyhydroxy compound and an epoxy-functional polysiloxane in the presence of a catalyst." (*See* Qureshi, paragraph [0015]). Continuing, Qureshi states that "[p]referably, the polyhydroxy compound is reacted with an epoxy-functional polysiloxane in the presence of the catalyst ***at a temperature***

of between about 180°C and about 250°C for about 1 to about 7 hours." (*See* Qureshi, paragraph [0015] (emphasis added)). Qureshi states that the cure time is the time when the resin is "***hard*** on the hot plate." (*See* Qureshi, paragraph [0015] (emphasis added)).

Therefore, Qureshi does not suggest macromonomers that are curable in vivo. In fact, Qureshi's relates to a high strength pultrusion resin whose preferred reaction conditions are adverse to in vivo conditions (*i.e.*, at a temperature of between about 180°C and about 250°C for about 1 to about 7 hours, whereas human body temperature is about 37°C and water boils at 100°C).

Although Qureshi does not disclose the specific mechanical properties of the cured elastomeric component, Qureshi states that "[t]he invention is directed to a ***high strength*** pultrusion resin composition." (*See* Qureshi, paragraph [0015] (emphasis added)). Furthermore, Qureshi states that the cure time is the time when the resin is "***hard*** on the hot plate." (*See* Qureshi, paragraph [0015] (emphasis added)). Therefore, Qureshi teaches away from a macromonomer which when polymerized forms a cured polymer having a relatively low elasticity (E) modulus "between 0.1 and 5 kPa," as recited in the present claims. Accordingly, the skilled person would not regard Qureshi as relevant and further would not be led from Qureshi to the present invention.

Furthermore, one skilled in the art would not have a reasonable expectation of success in obtaining the presently claimed subject matter. Claim 5 recites that the macromonomer "contains at least one pendant Z." The formula recited in claim 5 also requires at least one terminal Z. These requirements relate to "cross-link density" of the claimed macromonomers and are important in order to ensure that each macromonomer is cross-linked in vivo and does not leach from the site of polymerization as an "extractable." In addition, claim 5 recites that "the

macromonomer is curable in vivo and when polymerized to form a cured polymer, the polymer has an elasticity (E) modulus between 0.1 and 5 kPa." This relatively low modulus is important in order for the polymer to be manipulated by the ciliary muscles, for example, when the cured polymer is utilized as part of an intraocular lens. (*See* present specification at page 8, lines 1-4).

The use of terminal and pendant functional groups is not an obvious solution to obtain a macromonomer that is curable in vivo and has the recited elasticity modulus of claim 5 (*i.e.*, "between 0.1 and 5 kPa"). Where a macromonomer is terminally-functionalized and pendantly-functionalized, it is an efficient cross-linker and the modulus of a polymer formed from the macromomoner is expected to be higher than the range recited in claim 5. The obvious way to reduce the modulus to the range recited in claim 5 is by:

a) reducing functionalization of the macromonomers by not functionalizing some macromonomers at terminal or pendant positions (which may then result in some macromonomers not being cross-linked and leaching out – an unacceptable outcome for curing in vivo);

b) including a plasticizer in the macromonomer composition to "soften" the polymer (which plasticizer also may leach out – another unacceptable outcome for curing in vivo); or

c) increasing the average molecular weight of the macromonomer per functional group in order to "dilute" the functionalization (but this may unacceptably increase the viscosity of the uncured composition and hinder injection prior to curing in vivo).

The present inventors surprisingly have discovered that a combination of terminal and pendant functionalization achieves the requirements of claim 5 without these

unacceptable side effects. Qureshi does not suggest that the claimed subject matter would be expected.

For all these reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) over Qureshi are requested.

VI. Claim Rejections – 35 U.S.C. § 102(e) over Lutz *et al.*

Claims 1-5, 7-13, 15-20, 27-29, and 33 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Lutz *et al.*, (U.S. Patent No. 5,246,979)(hereinafter "Lutz"). The Office Action asserts that Lutz teaches acrylamide-functionalized polymers meeting all the limitations of the aforementioned claims at columns 3-5 and particularly, lines 12-30. The Applicants respectfully traverse the rejection in view of the foregoing amendments and for the following reasons.

Claim 1 has been cancelled and the pending claims depend either directly or indirectly from claim 5. Claim 5 has been amended to include, *inter alia*, the following limitations:

> "the macromonomer contains at least one pendant Z"; and
>
> "the macromonomer is curable in vivo and when polymerized to form a cured polymer, the polymer has an elasticity (E) modulus between 0.1 and 5 kPa."

Lutz does not teach or suggest a macromonomer meeting all of the limitations of claim 5. Therefore, Lutz does not anticipate the present claims. Although Lutz discloses general formulas for polydiorganosiloxanes at column 5, lines 12-30, Lutz does not teach or suggest the macromonomer of claim 5 as amended.

First, the Applicants have identified macromonomers that are suitable for curing in vivo. This aspect is recited in the present claims. Lutz does not teach or suggest macromonomers that are cured in vivo. Furthermore, after Applicants' macromonomers are polymerized to form a cured polymer, the polymer has a suitable elasticity (E) modulus, which is recited in the claims as "between 0.1 and 5 kPa." This limitation on the modulus is not taught or suggested by Lutz. Furthermore, this limitation on the modulus correspondingly places a structural limitation on the cross-linking density of the macromonomer that is not taught or suggested by Lutz.

In order to achieve the claimed aspects, claim 5 recites that the macromonomer "contains at least one pendant Z." In addition, the formula recited in claim 5 also requires at least one terminal Z. As noted above, these requirements relate to cross-link density of the claimed macromonomers and are important in order to ensure that each macromonomer is cross-linked in vivo and does not leach from the site of polymerization as an "extractable." Although Lutz states that "[t]he polyorganosiloxane has on the average at least 0.4 Z per molecule," (see column 5, lines 18-19), Lutz does not teach or suggest that it is required that each macromonomer include at least one ***pendant*** Z (and at least one terminal Z), as required in the present claims. In fact, for the lowest level of functionalization of Lutz's disclosed macromonomers, 3 out of every 5 macromonomers will not contain a cross-linkable group at all (on the basis that 0.4 = 2/5). In contrast, the macromonomers defined by the presently amended claims require at least one pendant Z and at least one terminal Z per macromonomer.

Surprisingly, as discussed above, the claimed macromonomers having terminal and pendant functionality can be cured in vivo to obtain a polymer having an elasticity (E) modulus of between 0.1 and 5 kPa. The recited modulus of the polymer is important in order for the polymer to be manipulated by the ciliary muscles, for

example, when the cured polymer is utilized as part of an intraocular lens. (*See* present specification at page 8, lines 1-4).

In summary, Lutz does not teach or suggest a macromonomer meeting all the limitations of the claims. In particular, Lutz does not teach or suggest a macromonomer having terminal and pendant functionality that is "curable in vivo and when polymerized to form a cured polymer, the polymer has an elasticity (E) modulus between 0.1 and 5 kPa." Furthermore, one skilled in the art would not have a reasonable expectation of success in obtaining a macromonomer having terminal and pendant functionality that is "curable in vivo and when polymerized to form a cured polymer, the polymer has an elasticity (E) modulus between 0.1 and 5 kPa." Lutz does not suggest that the claimed subject matter would be expected.

For all these reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e) over Lutz are requested.

VII. Claim Rejections – 35 U.S.C. § 103(a) over Lutz *et al.*

Claims 23 and 24 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lutz. The Applicants respectfully traverse the rejection in view of the foregoing amendments and for the following reasons.

Claim 23 has been cancelled obviating the rejection.

Claim 24 depends from claim 5. Therefore, for the same reasons discussed above with respect to claim 5, claim 24 is patentable over Lutz.

In addition, claim 24 further recites a macromonomer "having a molecular weight between 60,000 and 160,000." As discussed in the present specification, the molecular weight of the macromonomers and the level of functionalization are two important aspects for optimizing in vivo applications of the macromonomers. (*See*

specification, page 7, line 15, to page 8, line 16). The Office Action states that Lutz mentions "a polydimethylsiloxane bearing terminal acrylic groups with a degree of polymerization of 2000." (*See* Office Action at pages 5-6.) However, claim 24 also requires "at least one ***pendant*** Z" (and at least one terminal Z), based on dependency from claim 5. Lutz's disclosed polydimethylsiloxane with a degree of polymerization of 2000 does not include a pendant Z. None of the other polydimethylsiloxanes explicitly disclosed in Lutz meet the molecular weight limitation of claim 24 and include at least one pendant Z.

The macromonomers of the present invention must have at least one pendant and terminal Z group with the advantages of these features being described in the specification and discussed above. (*See* specification, page 7, line 15, to page 8, line 16). In particular, higher molecular weight macromonomers with more cross-linkable groups per chain (assuming cross-link density remains constant) contain a decreased amount of extractables. (*See* specification, page 7, line 26 to page 8, line 1). However, a higher molecular weight also causes a higher viscosity and therefore a decrease in the ease of injectability for curing in vivo. (*See* specification, page 8, lines 9-11). The present inventors have found that using a combination of both pendant and terminal cross-linkable groups results in a better ability to balance these competing considerations. (*See* specification, page 8, lines 14-16). That is, the macromonomers of the present invention are better able to provide decreased extractables, sufficiently low modulus, and sufficient viscosity for injectability for in vivo curing. These aspects are encompassed in the claimed subject matter.

In summary, Lutz does not teach or suggest a macromonomer where "the macromonomer contains at least one pendant Z" (and at least one terminal Z); and where "the macromonomer is curable in vivo and when polymerized to form a cured polymer, the polymer has an elasticity (E) modulus between 0.1 and 5 kPa"; and

where the macromonomer has "a molecular weight between 60,000 and 160,000." Furthermore, the present inventors surprisingly have discovered that a macromonomer having terminal and pendant functionalization and a molecular weight between 60,000 and 160,000 can be cured in vivo to obtain a polymer having an elasticity (E) modulus between 0.1 and 5 kPa. Lutz does not teach that this result is expected. Therefore, claim 24 is patentable over Lutz.

For all these reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) over Lutz are requested.

VIII. Claim Rejections – 35 U.S.C. § 103(a) over Hodd *et al.*

Claims 1-5, 7-13, 15-20, 22-24, 27-29, 32-33, and 35 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hodd *et. al.* (U.S. Patent No. 6,737,496)(hereinafter "Hodd"). The Applicants respectfully traverse the rejection in view of the foregoing amendments and for the following reasons.

Claim 1 has been cancelled and the pending claims depend either directly or indirectly from claim 5, which has been amended to recite a macromonomer where "the macromonomer contains at least one pendant Z" (and at least one terminal Z); and where "the macromonomer is curable in vivo and when polymerized to form a cured polymer, the polymer has an elasticity (E) modulus between 0.1 and 5 kPa."

First, Hodd does not teach or suggest a polymer having "an elasticity (E) modulus between 0.1 and 5 kPa," as required in the present claims. In fact, Hodd discloses a polymer with a modulus of "below about 55kPa and ***typically from 20 – 50 kPa***." (*See* column 6, lines 41-44 (emphasis added)). The polymers of the present invention typically have much lower moduli than the disclosed polymers of Hodd. (*See* present specification at Examples 4, 6, 8, and 11, which disclose polymers having "an elasticity (E) modulus between 0.1 and 5 kPa"). As discussed above, a lower

moduli allows the claimed lenses to be manipulated by the ciliary muscles. (*See* present specification, page 8, lines 1-4).

Furthermore, Hodd does not explicitly teach or suggest a macromonomer that contains at least one pendant and terminal Z group, as required in the present claims. The macromonomers of the present invention must have at least one pendant and terminal Z group with the advantages of these features being described in the specification and discussed above. Hodd does not teach, suggest, or even enable a macromonomer that contains at least one pendant and terminal Z group anywhere in its disclosure. The structure provided in Hodd at column 4, lines 45-51, does not allow pendant cross-linkable groups and none of the examples of Hodd demonstrate synthesis of polymers with pendant cross-linkable groups.

As discussed above, use of terminal and pendant functional groups is not an obvious solution to obtain a macromonomer that is curable in vivo and has the recited elasticity modulus of claim 5 (*i.e.*, "between 0.1 and 5 kPa"). Where a macromonomer is terminally-functionalized and pendantly-functionalized, it is an efficient cross-linker and the modulus of a polymer formed from the macromomoner is expected to be higher than the range recited in claim 5. The obvious way to reduce the modulus to the range recited in claim 5 is by:

a) reducing functionalization of the macromonomers by not functionalizing some macromonomers at terminal or pendant positions (which may then result in some macromonomers not being cross-linked and leaching out – an unacceptable outcome for curing in vivo);

b) including a plasticizer in the macromonomer composition to "soften" the polymer (which plasticizer also may leach out – another unacceptable outcome for curing in vivo); or

c) increasing the average molecular weight of the macromonomer per functional group in order to "dilute" the functionalization (but this may unacceptably increase the viscosity of the uncured composition and hinder injection prior to curing in vivo).

One skilled in the art would not be led by Hodd to prepare a macromonomer having terminal and pendant functionalization with the expectation that the prepared macromonomer could be cured in vivo to obtain a polymer having an elasticity (E) modulus of between 0.1 and 5 kPa.

For all these reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) over Hodd are requested.

IX. Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is requested to contact the Applicants' representative if a telephone interview will advance prosecution.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

M. Scott McBride
Reg. No. 52,008

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, WI 53202
(414) 271-7590